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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,470	10/16/2003	Warren Stern	SOHN-P01-001	8880

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FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
STITZEL, DAVID PAUL	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,470	STERN, WARREN	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 and 5-11 are drawn to a method for treating snoring, sleep apnea and other sleep related breathing disorders, wherein said method comprises administering a therapeutic agent for treating gastroesophageal reflux disease.

II. Claims 2 and 5-11 are drawn to a method for treating awake related respiratory impairment, wherein said method comprises administering a therapeutic agent for treating gastroesophageal reflux disease.

III. Claims 3 and 5-16 are drawn to a kit containing a pharmaceutical composition and instructions for administering said pharmaceutical composition, wherein said pharmaceutical composition comprises: a therapeutic agent for treating gastroesophageal reflux disease; and a pharmaceutically acceptable excipient.

IV. Claims 4-11 and 15-16 are drawn to a method of making a pharmaceutical composition for treating snoring, sleep apnea and other sleep related breathing disorders by administering said pharmaceutical composition for treating gastroesophageal reflux disease.

V. Claim 17 is directed to a business method.

1. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. In the instant case, the method

as claimed in Invention I has a function of treating sleep related breathing disorders, whereas the method claimed in Invention II has a function of treating awake related respiratory impairment. As a result, the method as claimed in Invention I has a materially different function from the method as claimed in Invention II and are therefore unrelated.

Inventions I and III are related as a method of using a product and a kit containing said product. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, a kit containing the product as claimed in Invention III can be used by another method that is materially different from the method claimed in Invention I. For example, as opposed to using said kit containing said product for treating a sleep related disorder as claimed in Invention I, said kit containing said product as claimed in Invention III may alternatively be used for treating an ulcer.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. In the instant case, the method as claimed in Invention I has a function of treating sleep related breathing disorders, whereas the method claimed in Invention IV has a function of making a product for treating sleep related breathing disorders. As a result, the method as claimed in Invention I has a materially different function from the method as claimed in Invention IV and are therefore unrelated.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. In the instant case, the method as claimed in Invention I has a mode of operation of treating sleep related breathing disorders, whereas the method claimed in Invention V has a mode of operation of conducting a medical assistance reimbursement program. As a result, the method as claimed in Invention I has a materially different mode of operation from the method as claimed in Invention V and are therefore unrelated.

Inventions II and III are related as a method of using a product and a kit containing said product. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, a kit containing the product as claimed in Invention III can be used by another method that is materially different from the method claimed in Invention II. For example, as opposed to using said kit containing said product for treating awake related respiratory impairment as claimed in Invention II, said kit containing said product as claimed in Invention III may alternatively be used for treating an ulcer.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. In the instant case, the method as claimed in Invention II has a function of treating awake related respiratory

impairment, whereas the method claimed in Invention IV has a function of making a product for treating sleep related breathing disorders. As a result, the method as claimed in Invention II has a materially different function from the method as claimed in Invention IV and are therefore unrelated.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. In the instant case, the method as claimed in Invention II has a mode of operation of treating awake related respiratory impairment, whereas the method claimed in Invention V has a mode of operation of conducting a medical assistance reimbursement program. As a result, the method as claimed in Invention II has a materially different mode of operation from the method as claimed in Invention V and are therefore unrelated.

Inventions III and IV are related as a kit containing a product and a method of making said product. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of making the product as claimed can be used to make a materially different product; or (2) the product as claimed can be made by another method that is materially different from the instantly claimed method of making said product. See MPEP § 806.05(f). In the instant case, a method of making the product as claimed in Invention IV can be used to make a materially different product from the product claimed in Invention III. For example, as opposed to making a product for treating sleep related breathing disorders as claimed in Invention IV, said method of making said product may alternatively be used for making a product for treating an ulcer.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. In the instant case, the kit containing a product as claimed in Invention III has a mode of operation of treating sleep related breathing disorders via the administration of a therapeutic agent for treating gastroesophageal reflux disease, whereas the method claimed in Invention V has a mode of operation of conducting a medical assistance reimbursement program by providing reimbursement for a prescription of a gastric secretion inhibitor. As a result, the kit as claimed in Invention III has a materially different mode of operation from the method as claimed in Invention V and are therefore unrelated.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. In the instant case, the method as claimed in Invention IV has a mode of operation of making a product for treating sleep related breathing disorders, whereas the method claimed in Invention V has a mode of operation of conducting a medical assistance reimbursement program. As a result, the method as claimed in Invention IV has a materially different mode of operation from the method as claimed in Invention V and are therefore unrelated.

Because these inventions are independent and distinct for the reasons given above and the prior art search required for each respective invention would be divergent, thereby causing an undue search burden, restriction for examination purposes as indicated is proper. Applicant is required under 35 U.S.C. § 121 to elect a single invention for prosecution on the merits.

2. Claims 5 and 6 are generic to a plurality of disclosed patentably distinct species comprising: 1. a histamine H_2-receptor antagonist (i.e., subspecies comprising: Tagamet, Zantac, Pepcid and Axid); 2. a proton pump inhibitor (i.e., subspecies comprising: formulas I-XVIII, Prevacid, Nexium, Prilosec, Protonix and Aciphex); 3. a bismuth compound; 4. a synthetic somatostatin analog; 5. an antiemetic agent; 6. a sucralfate; 7. a prostaglandin analog; 8. a muscarinic cholinergic antagonist; 9. a D2 antagonist; 10. a chenodeoxycholic acid; 11. an ursodeoxycholic acid; and 12. a pancreatic enzyme preparation. Because each of the disclosed species and subspecies are patentably distinct, each from the other, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, Applicant is required under 35 U.S.C. § 121 to elect not only a single disclosed species (i.e., a proton pump inhibitor), but also a single disclosed subspecies (i.e., a compound of formula XVIII), for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 5 and 6 are generic. Applicant should also include a chemical structure of the elected compound, if a chemical structure of said compound is not already contained within the instant specification.

Conclusion to Restriction Requirement

The Examiner has required restriction between product, methods of using, methods of making and business method claims. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn methods of using and methods of making claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of using

and methods of making claims that depend from or otherwise include all the limitations of the patentable product claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of using and methods of making claims will be withdrawn, and the rejoined methods of using and methods of making claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of using and methods of making claims may be maintained. Withdrawn methods of using and methods of making claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the methods of using and methods of making claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that a fully responsive reply to this requirement must include an explicit identification of not only a single disclosed species (i.e., a proton pump inhibitor), but

also a single disclosed subspecies (i.e., a compound of formula XVIII), that is elected consonant with this requirement, and a listing of all claims, including any claims subsequently added thereto, which are readable upon the elected species and subspecies. Applicant should also include a chemical structure of the elected compound, if a chemical structure of said compound is not already contained within the instant specification. An argument that a claim is allowable or that claims are not generic is considered nonresponsive unless accompanied by an explicit election of a specific species and subspecies. See 37 C.F.R. § 1.143.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species and subspecies to be obvious variants over one another or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

If claims are added after the election, Applicant must explicitly indicate which claims are readable upon the elected species. See MPEP § 809.02(a). Amendments submitted after final rejection are governed by 37 CFR 1.116, whereas amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an actual Inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Sreenivasan Padmanabhan can be reached at 571-272-0629. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER